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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,917	06/11/2001	Kathrin U. Jansen	20342P	1222
7590 10/19/2005			EXAMINER	
ALYSIA A. FINNEGAN C/O MERCK & CO., INC. PATENT DEPT., RY60-30 P. O. BOX 2000 RAHWAY, NJ 07065-0907			SALIMI, ALI REZA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,917

Applicant(s)

JANSEN ET AL.

Examiner

A R. Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Please note the application has been transferred to a new examiner, as Examiner Scheiner is no longer with Office. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Salimi.

Response to Amendment

This is a response to the amendment filed 6/16/2005. Claim 9 has been amended. Claims 1-12 are pending before the examiner.

The previously mailed Office Action is vacated in its entirety. A new office action is drafted below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Muller et al (Journal of Virology, Feb. 1995, Vol. 69, No. 2, pages 948-954).

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The claimed inventions are directed to human papillomavirus (HPV) virus-like particles (VLPs) covalently linked to a reporter wherein the HPV is selected from large family of papillomavirus types. Additionally, an assay to determine the presence of anti-HPV neutralizing antibodies is claimed.

The above cited art clearly anticipates the broad recitation of claims 1-6, 9-11. Muller et al disclosed a formation of VLP reporter construct complex. They formed a complex between various human papillomavirus types VLPs and a marker (see the abstract, and page 949, last full paragraph). Muller et al also taught the up-take of VLP-reporter plasmid complexes in tissue culture (see page 950, left column, 2nd full paragraph). In addition, they taught a blocking assay wherein up-take of VLP-reporter plasmid assay was reduced in presence of antibodies (page 951, right column, 1st full paragraph). Applicants are reminded that if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Thus, the product taught by Muller et al anticipates the now claimed product.

Alternatively, it would have been obvious for one of ordinary skill in the art to substitute the β -Gal marker as taught by Muller et al with another well-known marker, as selection of markers is rather routine in this art, especially given the skill level is rather high in this art. Additionally, the various molar ratios having large range of molar ratio are deemed to be a design choice. The invention as a whole is prima facie obvious.

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Jarrett et al (WO 93/00436).

The broad limitations of the claimed product is clearly anticipated by the teaching and claims of the above cited reference. Jarrett et al taught fusion of papillomavirus capsid protein to a marker (see claims 1, 7-9). Jarrett's et al claim 1 merits broad interpretation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowy et al (5,618,536 A), and Jarrett et al (WO 93/00436).

The claimed inventions are directed to human papillomavirus (HPV) virus-like particles (VLPs) covalently linked to a reporter wherein the HPV is selected from large family of papillomavirus types. Additionally, an assay to determine the presence of anti-HPV neutralizing antibodies is claimed.

Lowy et al taught chimeric papillomavirus like particles wherein capsid proteins can be fused to another protein such as L2 and other peptides in tandem (see the abstract and the claims). This only differs since they did not teach fusion of the VLPs to a well-known marker.

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Jarrett et al taught general fusion of papilloma virus L2 capsid and bovine papillomavirus capsid protein fused to a co-protein such as GST or β -Gal marker. They also taught virus neutralization assay see page 9).

Therefore, one of ordinary skill in the art at the time of filing would have been motivated by the above cited references to combine the fusion of Jarrett et al with Lowy et al to be utilized in papilloma virus cell uptake and a neutralization assay. Applicant is reminded that the product taught by Lowy et al naturally forms "pseudovirion." Moreover, Jarrett et al had already disclosed that capsid proteins can be fused to a marker. Thus, adding a marker to the product of Lowy et al is rather obvious, absent any unexpected results. Certain modification is seen as a design choice. Hence, the invention as a whole is prima facie obvious.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

10/17/2005


ALI R. SALIMI
PRIMARY EXAMINER